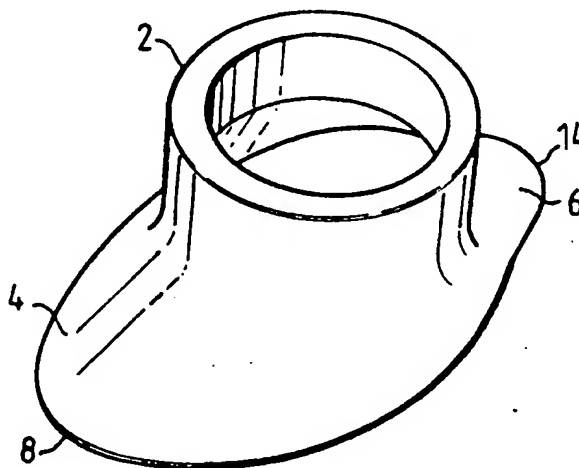




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(21) International Application Number:</b> PCT/SE94/00815 <b>(22) International Filing Date:</b> 5 September 1994 (05.09.94) <b>(30) Priority Data:</b> 9303155-7                      27 September 1993 (27.09.93)    SE <b>(71) Applicant (for all designated States except US):</b> ASTRA AKTIEBOLAG [SE/SE]; S-151 85 Södertälje (SE). <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only):</b> WIDERSTRÖM, Carin [SE/SE]; Höllvikstrandsvägen 77 B, S-236 00 Höllviken (SE). KARLSSON, Jan [SE/SE]; Ättevägen 4, S-245 62 Hjärup (SE). <b>(74) Agent:</b> SIVBORG, Susanne, Ås; Astra AB, Patent Dept., S-151 85 Södertälje (SE).		<b>(81) Designated States:</b> AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD).  <b>Published</b> <i>With international search report.</i>
<b>(54) Title:</b> FACE MASK  <b>(57) Abstract</b> <p>The present invention relates to a face mask for infants adapted to be provided on an inhalator device having a body, said mask comprising an annular adaptor part which is to be connected to one end of the body of the inhalator device, a funnel-shaped face engaging portion which with its narrow end is joined to one end of the adaptor part, the face engaging portion being made of resilient material, the wide end of the face engaging portion being adapted to be brought in engagement with the face around the mouth and at least a part of the nose of the infant and being resilient to be adaptable to the face, whereby the free edge of the wide end of the face engaging part is provided substantially in a plane which forms an angle of about 10°-25° with a plane perpendicular to the extended geometrical axis of the adaptor part.</p>		



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**FACE MASK**

5 The present invention relates to a face mask for  
infants adapted to be provided on an inhalator device  
having a body, said mask comprising an annular adaptor  
part which is to be connected to one end of the body of  
10 the inhalator device, a funnel-shaped face engaging  
portion which with its narrow end is joined to one end  
of the adaptor part, the face engaging portion being  
made of resilient material, the wide end of the face  
engaging portion being adapted to be brought in  
15 engagement with the face around the mouth and at least  
a part of the nose of the infant and being resilient to  
be adaptable to the face.

When dealing with bronchial diseases, such as asthma,  
among young children and infants, it is a problem to  
20 make them inhale the substances. When asthma makes its  
debute among young children such as infants from 8  
months up to 2.5 years it is especially difficult to  
make the infant inhale the prescribed medical  
substances correctly in the proper way. It is also a  
25 want among the parents that the used devices should be  
as flexible as possible.

**Background art**

30 It is known in the art to use stationary inhalation  
devices having expensive and complicated face masks  
which have shown to be very good also for infants. To  
use a stationary device could of course be inconvenient  
both for the infant and for the parents as they are  
35 bound to these stationary devices which are often  
placed in hospitals. As the inhalation capacity of an

infant is limited, the administration will be time consuming, which of course also is inconvenient.

5 Devices are also known in the prior art, which are intended to be used by older children and sometimes these devices are used also for infants even when the result of the inhalation is not satisfying.

10 An infant has a limited lung capacity and the force of the breath is limited. This is even more apparent when the infant is suffering from asthma or other bronchial diseases. The known devices are all constructed to be used by older children who have large lung capacity and who can inhale more forcefully.

15 The known devices are provided with one way valves to avoid the air from the exhalation to penetrate into the spacer body. These valves require a certain inhalation flow to open and an infant is not capable to generate  
20 the required inhalation flow to open the valve in the proper way.

EP 0 344 879 describes a face mask according to the preamble of claim 1 for use in connection with a device  
25 for inhalation of aerosols, where the face mask is connected to the spacer body and placed over the nose and mouth of the infant, see also EP 0 384 050.

30 The disadvantages with these face masks are that they present a rather large "dead space" between the valve in the spacer and the face mask, which requires a certain inhalation flow to insure that the substance to be inhaled does not stay in this "dead space", but reaches the lung area. Moreover, the shape of the face  
35 mask is not adapted to the face of an infant as it is round and the inhalation device is to be held in a horizontal position which makes inhalation difficult

for an infant. None of these two known devices is designed for the special needs of infants, who are suffering from bronchial diseases.

5     The invention

The face mask according to the present invention is intended to be used by infants and young children up to the age of about 2.5 years. In the following the word  
10     infant will be used to describe both an infant and an young child up to this age.

The face mask according to the invention is intended to be used in connection with a metered-dose aerosol  
15     inhalator for inhalation of aerosols, but could also be used together with any other inhalation device. A metered-dose aerosol inhalation device includes a holder for a medicament dispenser and an extended body, which in the technical field of inhalators normally is  
20     called a "spacer" or inhalation chamber, having an outlet provided at the end remote from the dispenser. Adjacent to the outlet an inhalation/exhalation valve is provided, preferably a so called one way valve, and at the outlet opening a mouthpiece is provided. When  
25     such a device is used by older children or adults the mouthpiece is inserted between the teeth and the lips are closed around the mouthpiece. It is however not possible for an infant to hold such a mouthpiece between its lips and therefore the inhalation device  
30     must be provided with a face mask when used by infants.

It is an object of the invention to provide a face mask for infants which overcomes the problems with the known face masks.

35

This and other objects are achieved by providing a face mask according to the invention with the characterising

features of claim 1, where the free edge of the wide end of the face engaging part is provided substantially in a plane which forms an angle of about  $10^{\circ}$  -  $25^{\circ}$  with a plane perpendicular to the extended geometrical axis of the adaptor part.

This inclination of the plane of the wide end of the face engaging portion makes it possible to decrease the dead space between the inhalation/exhalation valve and the mouth of the infant and makes it natural for the user to hold the inhalation device in an inclined position in relation to the infant's face in a manner which corresponds to the inclination of a baby feeding-bottle during feeding. This inclination will contribute to keeping the one way valve in the mouthpiece end of the spacer body of the inhalator opened. This is important because thereby resistance during inhalation is decreased. Through this inclination the dead space between the valve of the spacer and the mask could be decreased and kept as small as possible. Moreover the inclination of the mask and the spacer body makes it more comfortable for both the infant and the parent and as a result of the inclination the inhalation is improved.

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Other preferred embodiments of the face mask according to the invention are defined in the dependent claims.

#### Detailed description of the invention

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One preferred embodiment of the invention will now be described with reference to the drawings where

35

Fig. 1 shows a sectional side view of a face mask according to the invention,

Fig. 2 shows the face mask as viewed from above in Fig. 1,

Fig. 3 is a perspective view of the face mask, and

Fig. 4 shows a sectional side view of a second embodiment of the face mask.

In Figure 1 the face mask is shown in a side view. The face mask consists of two parts, a first part, the adaptor part 2, which is intended to be connected to the end of the spacer body of the inhalator (not shown) and a second part, the face engaging portion 4 which is intended to be held against an infants face during inhalation.

The adaptor part 2 is annular and preferably circular and has a length of preferably 12 mm. The thickness of the material in the adaptor part 2 is preferably about 5 mm.

The face engaging portion 4 is funnel-shaped and widens towards the free edge 10. The sides of the face engaging portion 4 are different in length, a short side 6 and a long side 8, as a consequence of the fact that the free edge 10 of the wide end of the face engaging portion is provided substantially in a plane which forms an angle  $\alpha$  of about  $10^\circ - 25^\circ$ , preferably  $15^\circ - 20^\circ$  with the plane perpendicular to the geometrical axis A-A of the adaptor part 2.

The circular adaptor part 2 smoothly merges with the face engaging portion 4 without any sharp edges or seams. At the junction between the two parts 2 and 4 of the face mask a shoulder 12 is provided. This shoulder is placed at the point where the thickness of the adaptor part 2 decreases from preferably about 5 to

about 2 - 3 mm, which is the thickness of the face engaging portion 4 at its base. The thickness of the material in the face engaging portion 4 decreases from about 2 - 3 mm at the junction with the adaptor part 2 to preferably about 0.5 mm at the free edge 10.

On the short side 6 of the face engaging portion 4 a nose engaging part 14 is provided which is meant to at least partly cover the nose of the infant during inhalation. The length of the short side 6 is preferably about 20 mm including the adaptor part 2 and the length of the long side 8 is preferably about 48 mm including the adaptor part 2.

The outer contour of the walls of the funnel-shaped face engaging portion 4 is concave and preferably forms an arc of an circle where the radius of the long side 8 is preferably about 40 mm and the radius of the short side 6 is preferably about 16 mm. The inner contour of the walls is convex and preferably also forms an arc of an circle where the radius of the long side 8 is preferably about 38 mm and the radius of the short side 6 is preferably about 20 mm.

As the different radii of the outer and the inner contours respectively have different centre points there will be a gradual decrease in thickness of the walls.

The funnel-shaped face engaging portion 4 has an oval form to adapt to the form of an infant's face. The ratio between the major axis (B-B) and the minor axis (C-C) is thereby 1.2 - 1.4, see Fig 2.

The free edge 10 and the adjacent part of the face engaging portion 4 are comparatively thin and therefore very flexible. When the face mask is placed around the mouth and at least part of the nose of an infant the



outer part of the face engaging portion can therefore well adapt to the face of the infant so that if required the mask can seal against the face in an air tight manner. This is especially important when the substance to be inhaled comprises steroids or other substances with which the eyes must not come into contact.

As can be seen in Fig. 2 the nose engaging part 14 can be shaped as a substantial semi-circular protrusion extending from the edge of the short side 6. With this protrusion the adaption to the nose of the infant is improved.

The nose part 14 could also be provided with a more inclined edge to better adapt to the shape of an infants nose. The outer edge of the nose part is thereby drawn backwards to the adaptor part 2 as shown in Fig. 4.

The mask according to the invention is preferably made of thermoplastic material or other rubber-like material being soft and resilient such as thermoplastic elastomers or silicon-like materials but of course other materials having similar properties could be used.

In the above reference has been made to treatment of asthmatic diseases by inhalation of suitable medical substances, but it is apperent that the face mask according to the invention also could be used for inhalation of other medical substances, such as for example anesthetics.

Reference is also made to the use of the face mask together with metered-dose aerosol inhalators, but the face mask could also be used together with any kind of

inhalators provided that they have an adaptor part at their mouthpiece end adapted to fit to the adaptor part of the face mask.

5     Possible modifications

The face mask could of course be modified within the scope of the appended claims.

10    Thus the inside of the adaptor part, which in the above described embodiment is provided with a shoulder in the transition between the adaptor part and the face engaging portion, could smoothly merge into the face engaging part.

15    Although, it is not necessary as the material and the thin thickness of the edge of the face mask makes it possible for the exhalation air to escape from the face mask and the inhalator, the face engaging portion could  
20    be provided with an exhalation hole to make the escape of the exhaled air easier during the inhalation treatment.

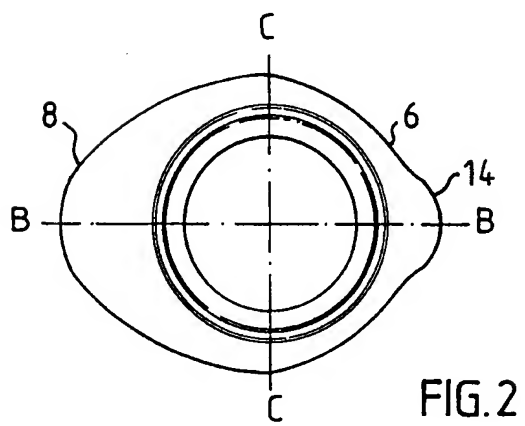
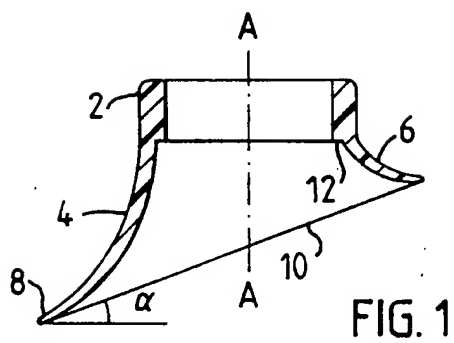
Claims

1. Face mask for infants adapted to be provided on an inhalator device having a body, said mask comprising an annular adaptor part (2) which is to be connected to one end of the body of the inhalator device, a funnel-shaped face engaging portion (4) which with its narrow end is joined with one end of the adaptor part (2), the face engaging portion (4) being made of resilient material, the wide end of said face engaging portion being adapted to be brought in engagement with the face around the mouth and at least a part of the nose of the infant and being resilient to be adaptable to the face, c h a r a c t e r i s e d in that the free edge (10) of the wide end of the face engaging portion (4) is provided substantially in a plane which forms an angle of about  $10^{\circ}$  -  $25^{\circ}$  with a plane perpendicular to the extended geometrical axis of the adaptor part (2).
2. Face mask according to claim 1, c h a r a c t e r i s e d in that a nose engaging part (14) of the face mask is provided at the short side (6) of the face engaging portion (4).
3. Face mask according to any of claim 2, c h a r a c t e r i s e d in that a protrusion (16) is provided on the nose part of the face engaging portion (4).
4. Face mask according to any of claims 1 to 3, c h a r a c t e r i s e d in that the outer side of the adaptor part (2) smoothly merges with the outer side of the face engaging portion (4).

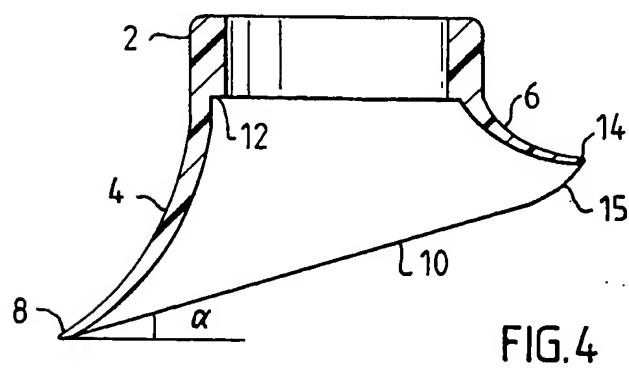
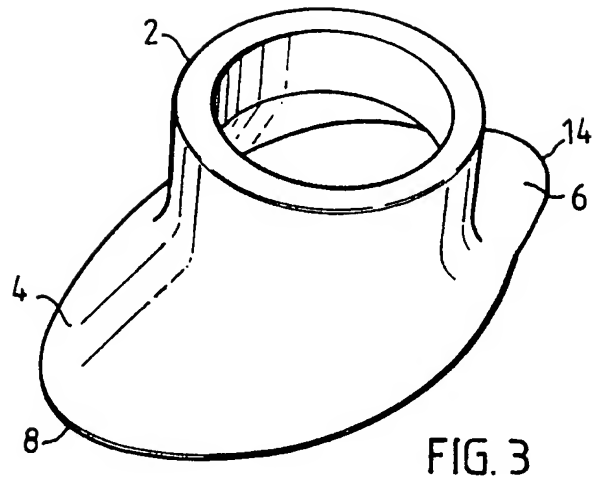
5. Face mask according to any of claims 1 to 4,  
c h a r a c t e r i s e d in that the outer contour of  
the face engaging portion (4) is concave and preferably  
describes an arc of an circle.
- 5 6. Face mask according to any of claims 1 to 5,  
c h a r a c t e r i s e d in that the inner contour is  
convex and preferably describes an arc of an circle.
- 10 7. Face mask according to claim 4,  
c h a r a c t e r i s e d in that an interior shoulder  
(12) is provided at the junction between the adaptor  
part (2) and the face engaging portion (4).
- 15 8. Face mask according to any of claims 1 to 7,  
c h a r a c t e r i s e d in that the free edge (10) of  
the face engaging portion (4) is oval.
- 20 9. Face mask according to any of claims 1 to 8,  
c h a r a c t e r i s e d in that the ratio between the  
major axis (B-B) and the minor axis (C-C) is 1.2 - 1.4.
- 25 10. Face mask according to any of claims 1 to 9,  
c h a r a c t e r i s e d in that the thickness of the  
wall of the face engaging portion (4) decreases  
gradually outwardly towards the free edge (10) of the  
face engaging portion.
- 30 11. Face mask according to claim 2,  
c h a r a c t e r i s e d in that the protrusion (16)  
is substantially semi-circular.
- 35 12. Face mask according to any of claims 1 to 11,  
c h a r a c t e r i s e d in that the face mask is made  
in one part.

13. Face mask according to any of claims 1 to 12,  
c h a r a c t e r i s e d in that the face mask is made  
of thermoplastic material or other similar material.

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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 94/00815

## A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 16/06

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 3042035 (G. COANDA), 3 July 1962 (03.07.62), page 1, figures 1,2, claims 1-8 --	1-4,8
X	WO, A1, 9301854 (DAHLSTRAND, MONIKA), 4 February 1993 (04.02.93), page 2, figures 1,2 -- -----	1-4,13

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

\* Special categories of cited documents:

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Date of the actual completion of the international search

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**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

26/11/94

International application No.  
PCT/SE 94/00815

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US-A-	3042035	03/07/62	NONE		
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WO-A1-	9301854	04/02/93	EP-A-	0595908	11/05/94
			SE-C-	500070	11/04/94
			SE-A-	9102205	20/01/93
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